

Applicants filed an Information Disclosure Statement on April 14, 2000. Although the first Official Action was dated April 13, 2000, Applicants respectfully submit that this first Official Action was not received until April 17, 2000. Accordingly, Applicants believe that no fee is required under 37 CFR §1.17(b) for the Information Disclosure Statement. However, if it is believed that such a fee is owed by Applicants, the Assistant Commissioner is authorized to charge any such fees to the Deposit Account No. 02-1666 or credit any overpayment thereto. Consideration of the Information Disclosure Statement filed on April 14, 2000, is respectfully requested.

The Examiner has rejected Claims 1-32 under 35 U.S.C. §112, second paragraph, as allegedly failing to distinctly claim the subject matter of the present invention. In order to further clarify the subject matter of the present invention, Applicants have amended Claims 1 and 13 pursuant to the Examiner's recommendations. The phrase "capable of" has been deleted and Claims 1 and 13 now have language that reads "...substance having a concentration effective for...". Therefore, withdrawal of this rejection is respectfully requested.

Claims 1-9, 13-16, 18, 25-27, 31 and 32 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Bresser et al. Claims 17, 19, and 20-24 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by, or alternatively, under 35 U.S.C. §103(a) as allegedly rendered obvious by Bresser et al. Claims 10-12 and 28-30 have been rejected under 35 U.S.C. §103(a) as allegedly rendered unpatentable by Bresser et al. in view of Hames et al.

Applicants have amended Claims 1 and 13 in order to further clarify the subject matter of the present invention. In Claim 1(a) and Claim 13(a), Applicants have added

the phrase "wherein the combined concentration of said first and second substances is greater than 30% of said composition."

The present invention describes a method for stabilizing the structure and nucleic acids of at least one cell in a sample, wherein said method comprises:

- (a) adding to a vessel containing the sample, a composition comprising a substance having a concentration effective for precipitating or denaturing proteins and effective for aiding in the infusion of said composition into said at least one cell, wherein the concentration of said substance is greater than 30% of said composition;
- (b) contacting said at least one cell in said sample with said composition;
- (c) incubating said sample with said composition for an effective period of time and at an effective temperature; and
- (d) obtaining said at least one cell with stabilized structure and nucleic acids in said sample.

The composition utilized in this method can also be comprised of a first substance for precipitating or denaturing proteins and a second substance to aid in the infusion of the first substance into the at least one cell, wherein the combined concentrations of the first and second substances is greater than 30% of the composition.

Bresser et al. do not teach, disclose or anticipate the claimed invention. In fact, Bresser teaches away from the concentration of the substance, or the combined concentration of the first and second substances, being greater than 30% (column 2, lines 62-64; column 3, lines 9-11; column 3, lines 27-30; column 4, lines 12-14; column 5, lines 21-23; column 5, lines 36-37; claim 1, column 17, lines 34-37; claim 30, column

19, lines 46-49; claim 53, column 21, lines 51-53; and claim 54, column 22, lines 11-13). In the method of the claimed invention the composition as amended has a substance having a concentration of greater than 30% of the composition, or the composition as amended has a combined concentration of the first and second substances being greater than 30% of the composition.

Although the claims have been rejected as anticipated under 35 U.S.C. §102(b) on the disclosure of Bresser et al., it is axiomatic that anticipation under Section 102 requires that the prior art reference disclose every element of the claim. In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986). Thus there must be no differences between the subject matter of the claim and the disclosure of the prior art reference. Stated in another way, the reference must contain within its four corners adequate directions to practice the invention. The corollary of this rule is equally applicable. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986).

Here it is clear that Claim 1 and 13 as amended and all claims dependent thereon differ from Bresser et al. Clearly, Kloster Speedsteel shows that Bresser et al. falls far short of the statutory standard of 35 U.S.C. 102(b). Claims 1-17 are not anticipated by Bresser et al. Withdrawal of the instant rejection under Section 102 is therefore respectfully requested.

The Examiner has alleged that Claims 17, 19 and 20-24 are rendered obvious under 35 U.S.C. §103 by Bresser et al. Applicants note that these claims are dependent on Claim 13 which has now been amended. Bresser et al. specifically teach away from the claimed invention as amended and thus do not teach or suggest the

claimed invention as amended. Withdrawal of this rejection under Section 103 is therefore respectfully requested.

The Examiner has alleged that Claims 10-12 and 28-30 are rendered obvious by Bresser et al. in view of Hames et al. Claims 10-12 are dependent on newly amended Claim 1 and Claims 28-30 are dependent on newly amended Claim 13. Bresser et al., the primary reference, specifically teaches away from the claimed invention and Hames et al., the secondary reference, provides no further teachings to enable one of ordinary skill to achieve the claimed invention. These references do not teach the claimed invention. Withdrawal of this rejection is thus respectfully requested.

In view of the above Amendments and Remarks, Applicants believe that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce S. Weintraub", with a large, stylized flourish at the end.

Bruce S. Weintraub  
Attorney/Agent for Applicant(s)  
Registration No. 34,277

BECTON, DICKINSON AND COMPANY  
1 Becton Drive  
Franklin Lakes, NJ 07417-1880  
(201) 847-7096  
p4579amend  
#35038